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| 09/558,576 | 04/26/2000 | Jeffrey A. Whitsett M.D. | CHMC7.001CP1 | 9558 |

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| EXAMINER | |
|---|---|
| SCHNIZER, HOLLY G | |
| ART UNIT | PAPER NUMBER |
| 1653 | 26 |

DATE MAILED: 06/18/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

FILE COPY

| Office Action Summary | Application No. 09/558,576 | Applicant(s) WHITSETT M.D., JEFFREY A. | |
|---|---|---|---|
| | Examiner Holly Schnizer | Art Unit 1653 | |

*-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --*

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

1)☒ Responsive to communication(s) filed on *28 February 2003* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

4)☒ Claim(s) *35-58* is/are pending in the application.

4a) Of the above claim(s) *45-53* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) *35-44 and 54-58* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

**Application Papers**

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on 4.26.00 is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. §§ 119 and 120**

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a)☐ The translation of the foreign language provisional application has been received.

15)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

**Attachment(s)**

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) *16* .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

## DETAILED ACTION

### *Continued Prosecution Application*

The request filed on February 28, 2003 (Paper No. 23) for a Continued Prosecution Application (CPA) under 37 CFR 1.53(d) based on parent Application No. 09/558,576 is acceptable and a CPA has been established. An action on the CPA follows.

### *Status of the Claims*

The Preliminary Amendment filed February 28, 2003 (Paper No. 23) has been entered and considered. Claims 1-34 have been cancelled and Claims 35-58 have been added. Therefore, Claims 35-58 are pending, Claims 45-53 are withdrawn from further consideration as being drawn to non-elected subject matter (see Switch of Inventions and Restriction below), and Claims 35-44 and 54-58 have been examined on the merits in this Office Action.

### *Switch of Inventions*

Applicants indicate that they wish to switch to the election of Group II (drawn to a method of treatment comprising introducing an SP-D protein (see p. 5, 2nd paragraph from the bottom of Paper No. 23 filed February 28, 2003).

A change in election may be made in a CPA when filed as a divisional or as a continuation including an amendment filed prior to a first action in the CPA adding claims to an invention not previously elected as in the present case. In each of these examples, the examiner should make a new restriction requirement in the first action

(see MPEP 819, last paragraph). In the present case, the new claims include subject matter from both Groups II and III of the original restriction requirement (see Paper No. 4). Therefore, the restriction requirement mailed October 10, 2000 (Paper No. 4) will be repeated below as it applies to the present claims.

***Restriction/Election***

Restriction to one of the following inventions is required under 35 U.S.C. 121:

II. Claims 35-44 and 54-58, drawn to a method of treatment comprising introducing a Surfactant Protein-D (SP-D) protein, classified in class 514, subclass 12.

III. Claims 45-53, drawn to a method of treatment comprising introducing a vector expressing an SP-D protein (gene therapy), classified in class 514, subclass 44.

The inventions are distinct, each from the other because of the following reasons:

Inventions II and III are mutually exclusive and independent. Invention II requires the active agent to be SP-D protein delivered directly. Invention III requires the active agent to be a vector expressing the SP-D protein delivered directly. The protocols for the treatments are materially different and separate because they have different starting materials, starting points, and method steps. Further, the method of treatment of Invention II is not required for the method of treatment of Invention III.

Having shown that these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification and

recognized divergent subject matter as defined by MPEP §808.02, the restriction for examination purposes as indicated is proper.

As indicated above, Applicants elected Group II drawn to a method of treatment comprising introducing SP-D protein (see Paper No. 23, filed February 28, 2003 at p. 5, second to last paragraph).

***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 35-44 and 54-58 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 35-44 and 54-58 are rejected because the acronym, SP-D, could represent more than one type of protein (substance P is often abbreviated SP, for example). Amendment of the independent claims to include "surfactant protein-D" followed by the abbreviation in parenthesis would clarify this ambiguity and overcome this rejection.

Claims 35-44 and 54-58 are indefinite as to when the SP-D protein is considered "substantially purified". The specification does not define what is meant by "*substantially* purified"(emphasis added). To purify implies to isolate something away from contaminants. However, the confusion arises because the claim is unclear as to what is considered a contaminant and how much purification is considered "substantial".

For example, the prior art teaches a method of treating pulmonary disease by administering surfactant; a mixture comprising lipids and proteins including SP-D (see Jobe et al. Am. Rev. Respir. Dis. (1987) 136 : 1256-1275 ; cited in Paper No. 10 and Lu et al. Biochem. J. (1992) 294: 795-802, Introduction; cited in Paper No. 15). The surfactant used in the methods, and therefore, SP-D contained therein, is purified away from its natural source. Is the SP-D in this composition encompassed by "substantially purified"? Would SP-D contained in surfactant lacking the other surfactant proteins (purified from an SP-A knockout mouse (a mouse lacking SP-A) for example) be considered "substantially purified"? The claim is unclear as to which and how much of the other surfactant proteins should be eliminated from the SP-D composition to be considered "substantially purified".

The rejection can be overcome by more clearly distinguishing the SP-D composition used in the claimed method from that of natural surfactant. The examiner offers the following suggestions as examples of amendments that would overcome this rejection:

1—in Claim 35, replace the phrase "introducing a composition comprising substantially purified mammalian SP-D protein" with –administering a recombinant mammalian surfactant protein-D (SP-D)--. This amendment would more clearly indicate that it is SP-D itself that is being administered and rather than surfactant. Or,

2—In Claim 35, replace "comprising" with –consisting essentially of--. The transitional phrase "consisting essentially of" would more clearly define the scope of the claim to the use of SP-D and other materials that do not materially affect the basic and novel

characteristics of the claimed invention. Thus, this limitation would exclude the use of surfactant compositions or other surfactant proteins or lipids.

***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) and the Intellectual Property and High Technology Technical Amendments Act of 2002 do not apply when the reference is a U.S. patent resulting directly or indirectly from an international application filed before November 29, 2000. Therefore, the prior art date of the reference is determined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

Claims 35-39, 54, and 58 are rejected under 35 U.S.C. 102(e) as being anticipated by Cochrane et al. (US Patent No. 6,013,619).

Cochrane et al. teach a method of treating pulmonary diseases such as pulmonary infection (see Col. 4, lines 53-65) by administering a surfactant. Cochrane et al. state that proteins derived from natural surfactant protein are useful in the methods disclosed therein (Col. 20, lines 24-27) and that natural surfactant proteins include SP-D, either alone, or in combination with lipids (Col. 20, lines 29-31). A proteins function is

an inherent property of its structure. Therefore, decreasing levels of phosphatidylcholine in the lung, inhibiting metalloproteinase activity, and reducing reactive oxygen species, all inherent activities of the SP-D protein, would be inherent results of the administration of the SP-D protein to the lung in the method of Cochrane et al.

***Conclusions***

No Claims are allowable. It is noted that the prior art of record does not appear to teach or suggest a method of treating pulmonary diseases using surfactant protein D that is purified away from its natural surfactant composition. The prior art does teach studies in vitro that suggest that SP-D could enhance pulmonary clearance of bacteria (Kuan et al.; cited in IDS filed 1-8-01 (Paper No. 25)) and viruses (Hartshorn et al.; cited in IDS of Paper No. 16; and Reid; cited herein and discussed below). However, Johannson et al. (cited in Paper No. 10) teaches that SP-D enhances the production of oxygen radicals (see p. 382, Col. 2, section 2). The Declaration under 37 CFR 1.132 by Jeffrey Whitsett states that one of skill in the art would not be motivated to treat inflammatory diseases of the lung using SP-D with the knowledge that SP-D increases superoxide production because superoxide production correlates with increased inflammation. Whitsett indicates that experiments done in the in vivo mouse model show the unexpected result that SP-D does not increase inflammation but actually decreases inflammation. Therefore, in light of the Whitsett declaration and absent any evidence to the contrary, it appears that the method of using SP-D in the treatment of

pulmonary disease would not have been obvious to one of ordinary skill in the art at the time of the invention because it was thought that SP-D would result in increased inflammation and a reduction of uncontrolled inflammation was the goal of such a treatment.

Related art cited but not relied upon:

Hickling et al. (1999) Eur. J. Immunol. 29 : 3478-3484 : Hickling et al. state that they provide the first in vivo evidence that a collectin (SP-D) can inhibit viral infectivity.

Borron et al. (Nov. 1998) J. Immunol. 161: 4599-4603) show in vitro that SP-D has an inhibitory effect on T-cell proliferation by anti-CD3, PHA, and ConA

Reid K.B.M. (1998) Immunobiol. 199: 200-207: Reid provides a review of the functional roles of SP-D in immunity and provides evidence that, at the time of the present invention, it was commonly thought in the art that SP-D would enhance the production of oxygen radicals by alveolar macrophages and neutrophils (see p. 204, lines 3-4).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Holly Schnizer whose telephone number is (703) 305-

3722. The examiner can normally be reached on Monday through Wednesday from 8 am to 5:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christopher Low can be reached on (703) 308-2923. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 308-4242 for regular communications and (703) 308-4242 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703 308-0196.

Holly Schnizer
June 16, 2003

CHRISTOPHER S. F. LOW
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